CAT II *invento*™

STANDER

CE

USER MANUAL

Our passion – your independence!

AKCES MED

5 903240 632879

CAUTION! Manufacturer takes responsibility for proper usage of the device only when the product was purchased from qualified Akces-Med employee or at specialized medical store!

CAUTION! AKCES-MED Ltd. reserve the right to introduce technical and trading changes in the content of the instruction without warning.

Medical product first class according to the Regulation 93/42/EWG of European Parliament and Council regarding medical products. For this product the producer issued relevant declaration of conformity. Producer's identification number in the Registration Department of Healing Products, Medical Products and Biocide Products: **PL/CA01 04088/W**

Akces-Med. Sp. z o.o. Company introduced quality management system ISO 13485 regarding production, sales and service. The system is certified by Det Norske Veritas.

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SYSTEM ZARZĄDZANIA JAKOŚCIĄ ISO 13485

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INTRODUCTION

Standing frame **CAT II INVENTO™** was designed to help during rehabilitation of children with paresis of lower limbs and trunk in order to enable those children taking the upright position. It is designed for active rehabilitation of handicap children. It enables independent (with supervision), safe standing, play and education.

Thanks to its simplicity **CAT II INVENTO™** is a valuable device in rehabilitation of handicap children at home, hospitals, rehabilitation centers. Used properly may significantly improve the quality of life of children.

Due to the usage of wood, colorful upholstery, bright colors and nice figure of cat children tend to treat the device more like a toy than the rehabilitation device.

It is a very universal device, very flaccid children can be put in it in upright position as well as children with huge muscle tone. Its universal character comes from wide range of proposed adjustments.

Please, read this manual carefully. Here you will find information regarding our product and you learn how to use it safely and effectively.

If you have any questions or comments please, contact our medical consultant (ph. 0048 508 382 502) or directly the AKCES-MED Customer Service (ph. 0048 17 864-04-70).

Thank you for purchasing our product.

CAUTION! Before using the product, user is obliged to familiarize himself/herself with user manual. Remember that complying with guidelines is highly important. It assures safety and extends durability as well as aesthetics of the device.

1 THE PURPOSE OF USER MANUAL

This manual contains information necessary for correct use of standing frame **CAT II INVENTO™**, preparation of the device before the use, maintenance and cleaning as well as the guarantee conditions. Manual should be kept in an easy accessible place.

The manual is addressed to the people who take direct care of handicap children, doctors and physiotherapists how handle the device.

CAUTION! Before using the product, user is obliged to familiarize himself/herself with user manual.

Please, remember that following the rules of the manual enables safe use of the product, its extended life and esthetics.

2 INDICATIONS FOR USE

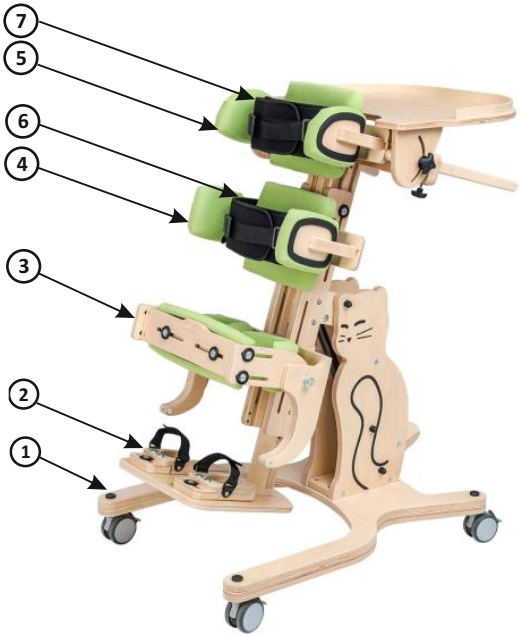
The device is recommended for people in the following cases:

- Cerebral palsy – different types.
- Demyelinating disease (children's multiple sclerosis, etc.).
- Brain and spinal cord damage of different etiology.
- Muscle disease with paresis and paralysis.
- Genetic syndromes with limb paresis.
- Other diseases with paresis, paralysis, or movement disorders.
- After traumatic brain or spine injury with spinal cord and lower limbs damage.

3 GENERAL CHARACTERISTICS OF STANDER

3.1 Standard equipment

1-foot rest with street castors with gas spring
2-foot stabilization
3-knee stabilization
4-pelvis supports
5-chest supports
6-pelvis stabilizing belt
7-chest stabilizing belt
8-head rest (used during supine standing)
9-tray



3.2. Additional equipment

KT_012 Cotton headrest cover

KT_023 Soft cover for tray

KT_003 3D foot adjustment

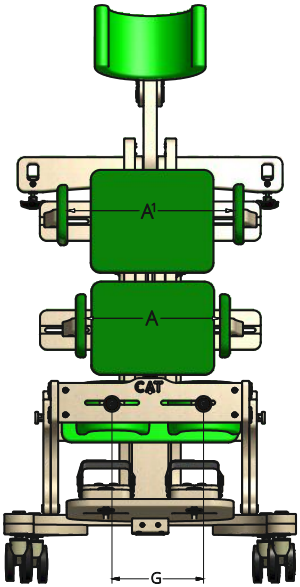
KT_005 Tray with bowl

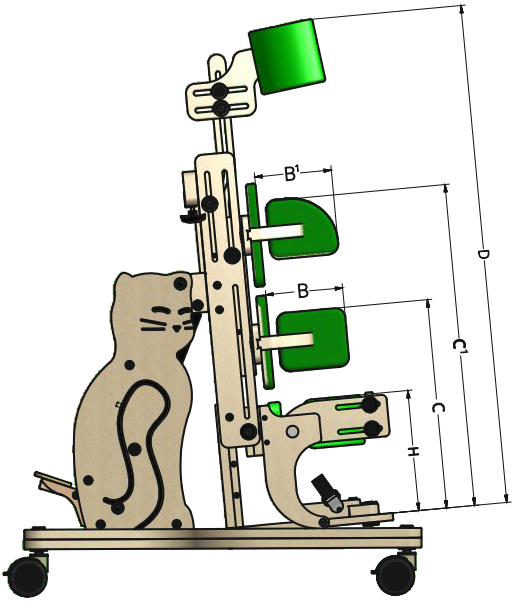
KT_001 Tray for manual therapy

KT_004 Head supporting belt

KT_124 Tango wheel

4 SIZE TABLE





Symbol	Measurement	Unit	Supine position	Prone position
A	Hip support width	[cm]	18-31	18-31
B	Hip support depth	[cm]	15	15
C	Foot rest to top of hip support	[cm]	27-78	40-78
A1	Chest support width	[cm]	18-31	18-31
B1	Chest support depth	[cm]	15	15
C1	Foot rest to top of chest support	[cm]	50-97	65-97
D	Foot rest to top of head rest	[cm]	80-135	-
G	Knee support width	[cm]	14-23	14-23
H	Foot rest to knee support	[cm]	15-54	15-54
	Upright position angle	[°]	0-90	
	Maximum user weight	[kg]	45	

	Weight and dimensions of the device	Unit	
	Product width	[cm]	60
	Product length	[cm]	81
	Product height	[cm]	90
	Product weight	[kg]	26

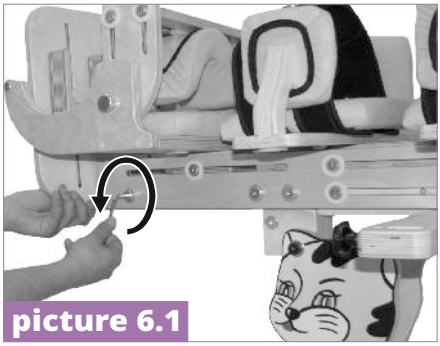
Note: Dimensional tolerance in the table is +1/-1 cm.

5 DESRIPTION HOW TO USE STANDER

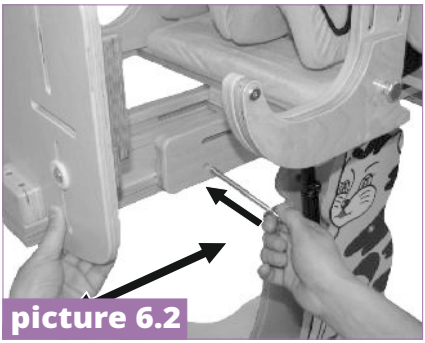
5.1 Adjustment of the foot rest

This is the main adjustment to the height of the user.
In order to do that it is necessary to:

- remove the screw located in the lower part of the standing frame using the 5mm key (point 11 page 6) included with the device (picture 6.1)
- place the foot rest in the required position (picture 6.2)
- insert the screw into the whole and tighten it with the key (picture 6.2)



picture 6.1

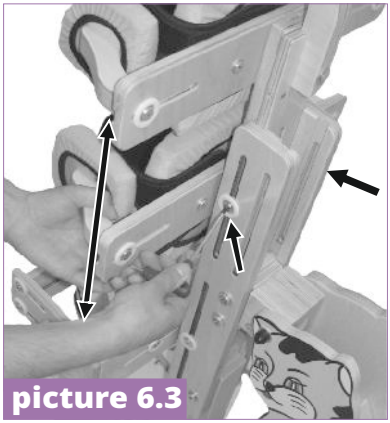


picture 6.2

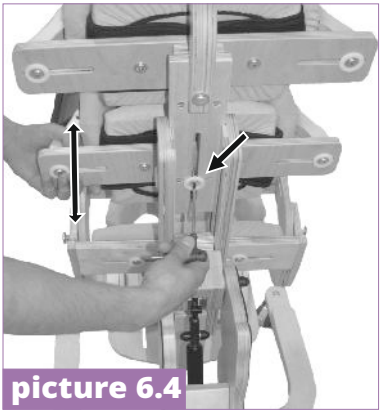
5.2 Adjustment of back stabilization

In order to properly adjust the back stabilization it is necessary to:

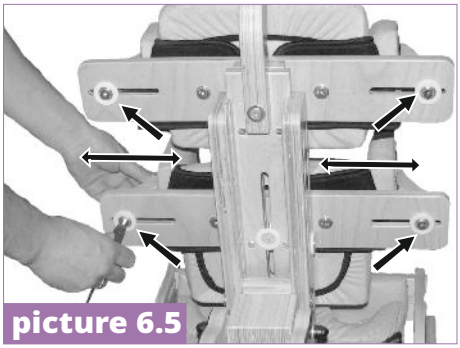
- remove the screws, place the back rest in the required position , insert the screws back into the wholes and tighten them (picture 6.3)
- adjust the pelvis supports (picture 6.4)
- adjust the distance between chest and pelvis supports (picture 6.5)



picture 6.3



picture 6.4

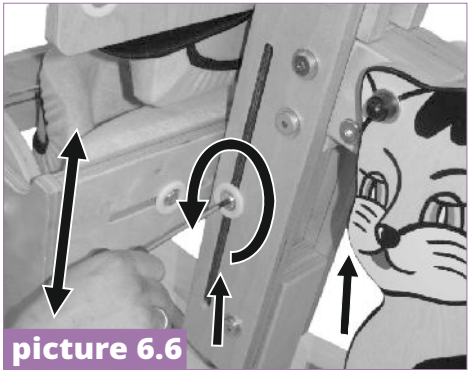


picture 6.5

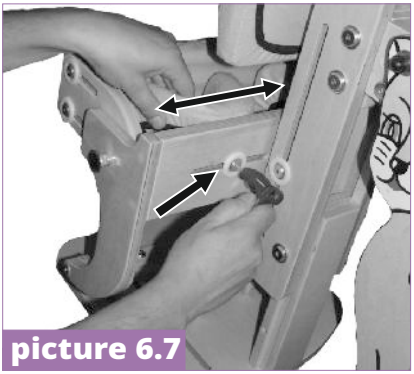
5.3 Adjustment of knee stabilization

In order to properly adjust the knee stabilization it is necessary to:

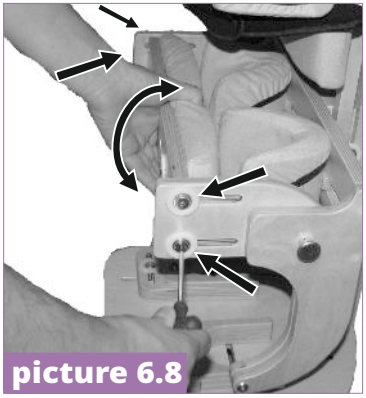
- adjust the height of the knee stabilization (pict. 6.6)
- adjust the distance between the knee supports (pict. 6.7)
- place the knee cushion in the required position (pict. 6.8)
- to prepare the device to the supine position additionally the knee supports must be adjusted (pict. 6.9)



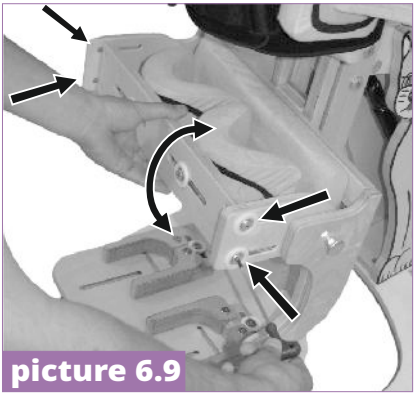
picture 6.6



picture 6.7



picture 6.8



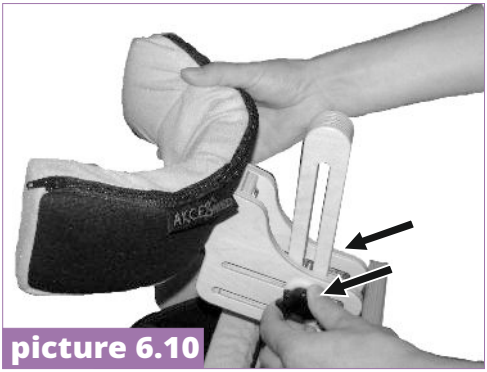
picture 6.9

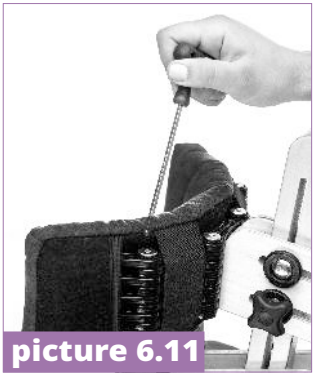
5.4 Adjustment of head rest

The head rest is used in supine position.
The adjustment is presented in chapter 8 on picture 1.

In order to properly adjust the head rest it is necessary to:

- adjust the correct height, angle of head position towards the body (pict. 6.10)
- shape the head rest to fit patient's head (pict. 6.11)



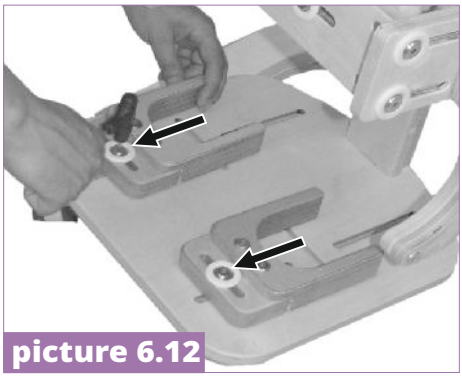


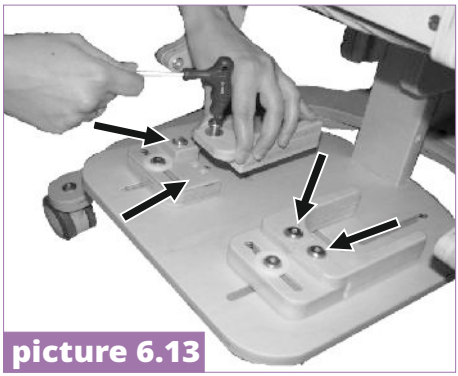
5.5 Adjustment of foot stabilization

a) heel stabilization

In order to properly adjust the heel stabilization it is necessary to:

- adjust the location and the distance between the heel stabilizations (pict. 6.12)
- adjust the width of heel stabilization to fit the shoes of the patient (pict. 6.13)

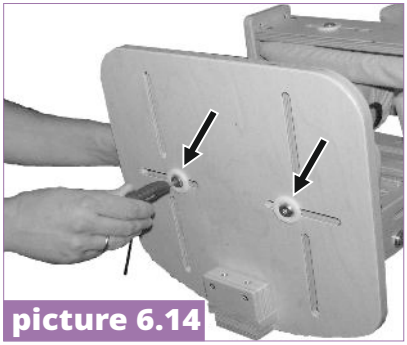

picture 6.12

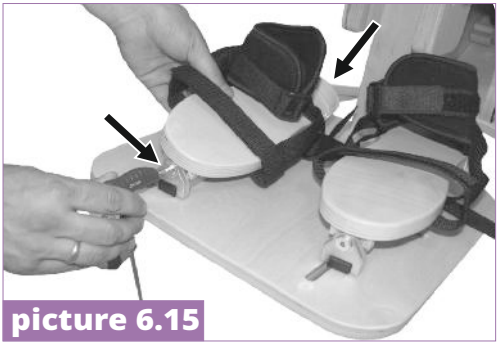

picture 6.13

b) footers with 3D adjustment (optional equipment)

If the device is equipped with 3D footers you have to adjust:

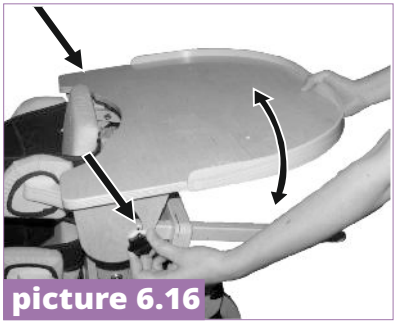
- location and distance between the footers (pict. 6.14)
- lateral inclination of the footers (pict. 6.15)

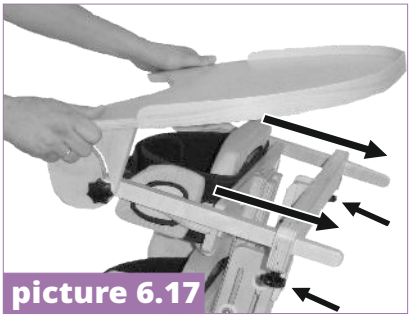

picture 6.14

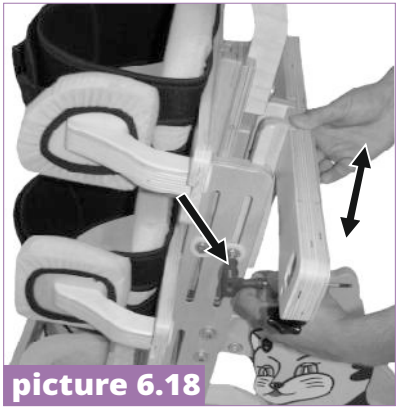

picture 6.15

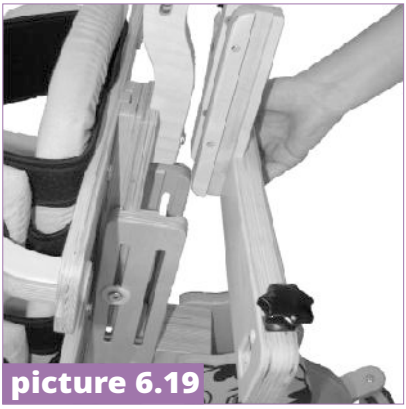
5.6 Adjustment of tray

The pictures 6.16, 6.17, and 6.18 present the way to adjust the height, assembly and tilting angle of the table.
If standing in the supine position additionally requires lowering the tray below the standard, turn the support as it is presented in the picture 6.19.


picture 6.16


picture 6.17


picture 6.18

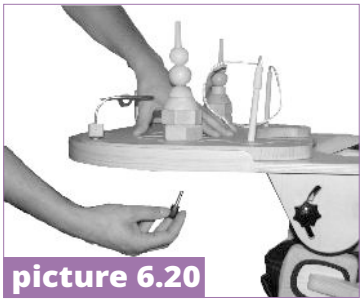

picture 6.19

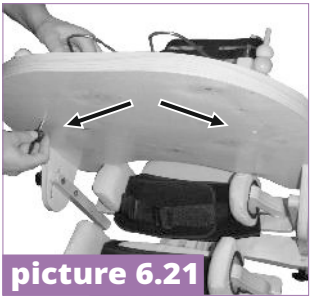
CAUTION! The adjustment of the tray in the supine position must be done after the patient is placed in the device. In case of prone position the tray is adjusted before the patient is placed in the device!

6 Additional equipment

6.1 Table for manual therapy

The table for manual therapy is assembled after the patient is placed in the device. The table for manual therapy is placed on the normal table and fixed to it with 2 screws (pictures 6.20 and 6.21).


picture 6.20


picture 6.21

6.2 Head supporting belt

Head supporting belt is attached to the back of the head rest (picture 6.22). It is used only if the device is in supine position.

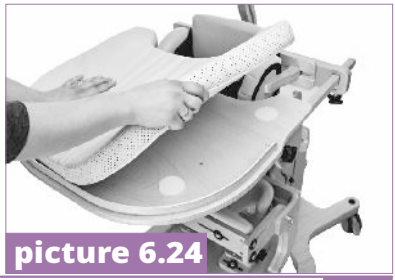
picture 6.22

6.3 Soft cover for tray

Please follow these steps so as to mount soft cover for tray:

- Adhere 5 adhesive Velcro tapes;
- Put soft cover in a way that its edges cover tray edges.

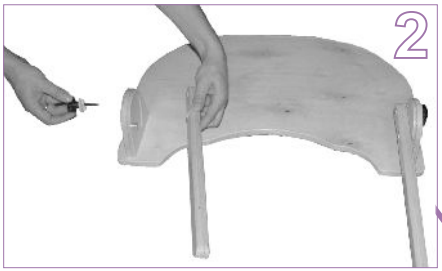
picture 6.23

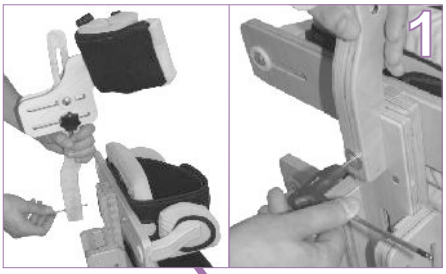

picture 6.24

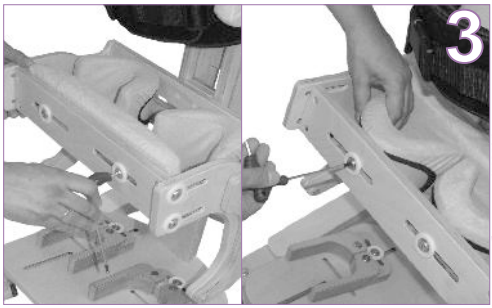
7 Adjustment of the device to the supine

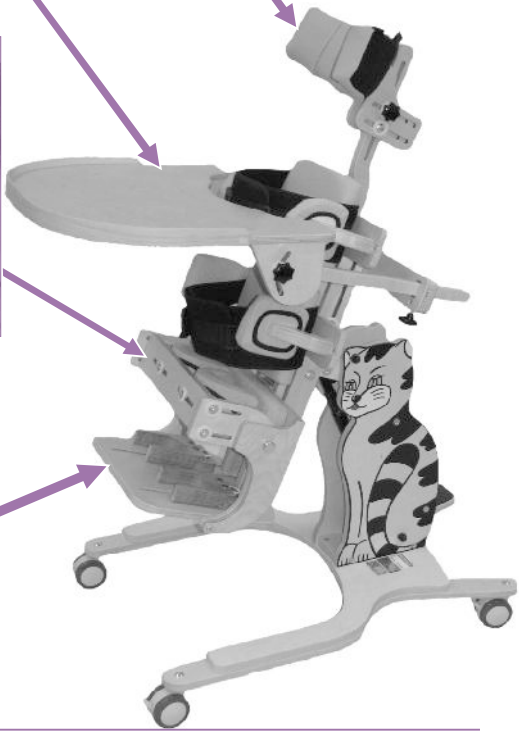
In order to prepare the device for standing in supine position it is necessary to:

1- assemble the head rest
2- change position of the tray support
3- assemble knee supports on the other side of the knee stabilization
4- change position of the heel stabilization in the footers









8 THE USE OF STANDER

CAUTION! Stander **CAT II INVENTO™** has to be used with compliance to guidelines included in this user manual. Remember to use the product only with someone who is trained and knowledgeable.

8.1. Preparation of the patient

Before using the product, it is essential to make sure that:

- patient's outfit is light and comfortable sporty clothes are advisable,
- shoes should be comfortable and, moreover, they should stabilize ankle,
- due to hygienic reason and to avoid abrasion it is advisable for the patient to always wear clothes when using the device, skin must not be naked especially in places of regular contact with upholstery,
- drains, bags, catheters etc. if applied, have to be secured to function properly and not to disturb during using the product,
- if it is necessary for a patient to wear orthopedic supply (collar, corset, orthesis, shoes) if it is recommended by doctor.

CAUTION! Outfit should protect patient's skin from direct contact with upholstery as well as other parts of equipment.

CAUTION! Only doctor can make a decision concerning using any kind of orthopedic supply!

8.2 Preparation of device before each use

CAUTION! It is highly important to adjust the device to the patient before using it!

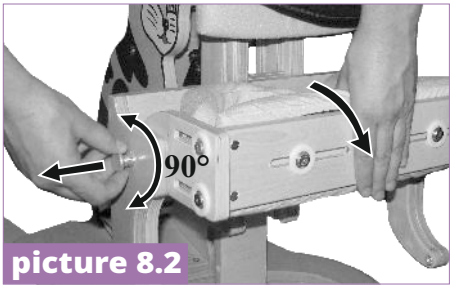
1. Before use it is necessary to:
   - unfold the device;
   - place the device on even ground in a way that it is easy to reach standing frame and person who sits inside; remember to keep standing frame away from fire and high temperature
   - make sure that all parts are serviceable, correctly mounted and stable
   - check castors and brakes
   - lock brakes
   - press brakes so as to lock all castors

Regarding standard equipment, the device is created for upright position forwards. Chapter 7 clearly shows how to adjust the device for upright position backwards.

CAUTION! Decision regarding prone or supine position is taken by the leading doctor or therapist!

- adjust the device to the patient
- place the device in lying position pressing the pedal with your foot (pict. 8.1)
- undo the chest stabilizing belts, pelvis stabilizing belts and foot and head stabilizing belts (if the device is equipped)
- open the knee stabilization, releasing the catch hold and turning it by 90°(pict. 8.2)

picture 8.1



picture 8.2

Equipment works correctly only when the device is adjusted according to patient's height as well as weight. Remember to take all these measurements into account while purchasing the product. Correct adjustment is the most important due to the fact that only then the product is safe. It is forbidden to force child to keep specific position because he/she will feel uncomfortable and it may lead to wrong posture.

CAUTION! First adjustment of standing frame can be performed only by someone who is traned. Further adjustment is performed by patient's relatives who had proper training concerning the usage as well as adjustment of this device. Remember that correct adjustment is essential due to the fact that the product is safe and, moreover, the rehabilitation process is proceeding correctly.

CAUTION! Remember to make sure that all belts and locking are correctly adjusted and fastened. Check also if fastenings from adjustable elements are firmly tightened.

8.3. Upright position

In order to have upright position it is necessary to:
1. Prepare place where upright position process will take place. It should be a place without any dangers (toys scattered all over the floor or any different objects).
2. Place standing frame as close as possible to the patient.
3. Lock castors from standing frame, stroller or any different device in which the patient is seated
4. Place patient in standing frame and make sure that all adjustment is correct. Make changes if necessary (fig.10.2 and fig.10.3)

5. Fasten the patient with the aid of all belts and close knee support. Make sure that all castors are situated in correct places (fig. 10.4)

picture 10.1

6. Make sure that all belts and locking are correctly adjusted and fastened.
7. Unlock standing frame with the aid of pedal and hold patient as well as upper movable part of the device at the same time. Place the patient in proper position and then lock the device by releasing pedal.
8. Fix table (concerning upright position backwards).
9. Do everything the other way around when it is necessary to take out the patient from the device

CAUTION!

The length of time for upright position process is different for each patient. It is recommended to extend this time during the initial period (adaption period for the change of position). Either doctor or physiotherapist can make decision concerning the length of upright position process. Upright position process has to be always performed under the supervision of trained person!

It is recommended to divert patient's attention during upright position process by:
- manipulation games
- educational games
- touch stimulation and others

CAUTION! As far as first upright standing is concerned, it takes place in rehabilitation, neurosurgery or orthopedics wards. Moreover, it has to be performed together with doctor and physiotherapist due to the fact that medical problems may appear during first treatments such as fainting, drop in blood pressure, dizziness etc. Upright standing is continued in home together with trained staff (rehabilitation technician, district nurse, trained family members).

CAUTION! Incorrect adjustment of the device can lead to side effects such as: fainting, body deformities, overloading joints. It is highly advisable to adjust the device before every use of a standing frame. This adjustment has to be done only by a trained person or therapist. If any of these side effects appear, it is highly important to stop the upright position process, take out the patient from the device and lie him/her down. If these undesirable side-effects still occur it is necessary to contact doctor. If these side effects disappeared, remember to inform doctor so as to make decision concerning further upright position process.

9 SAFETY RULES

CAUTION! Stander **CAT II INVENTO™** has to be used in compliance with guidelines in this user manual.

It is highly important to consult either doctor or physiotherapist in order to make right decision concerning the choice of **CAT II INVENTO™** and its size. It is also essential to familiarize with the guidelines described in user manual before using the device.

1. Before use it is necessary to:

- make sure that there are no damages or different faults which could endanger patient's life; check if all parts are working and are correctly mounted and, moreover, check if they are not broken;
- check if all screws, knobs and all glued, sewed or tapped parts are tightened;
- check if brakes are operating correctly;
- check if buckles are operating correctly;
- always use safety belts, Velcro tapes should overlap min. 8cm;
- adjust the device according to patient's measurements and needs e.g. the adjustment of pelottes , footplate etc.;

- make sure that all movable parts and knobs for adjustments are stable and locked;
- secure patient with the aid of elements such as vest, foot stabilizing belts, pelottes, abduction block, headrest. It is highly important to secure patient because it safeguards him/her from falling out. If abduction contracture occurs, it is recommended to use abduction block in order to prevent ulcers between knees.

2. It is forbidden to use the device for different purposes that it is intended to.
3. It is forbidden to use the device when it is damaged or any part is missing.
4. It is forbidden to leave the patient unattended.
5. The device should be used only when there is someone who is trained and knowledgeable.
6. It is forbidden to leave the device and the patient on unstable ground unattended, even if the brake is engaged.
7. It is forbidden to either go up or down the stairs; it doesn't matter if the patient is placed in the device or not.
8. It is important to engage brake during getting into and getting out the device.
9. Make sure that all limbs are not close to spokes or other adjustable elements.
10. Although the device and the upholstery are made of fire-resistant materials, please pay your attention when approaching to sources of fire or sources of high temperature during using the device. Moreover, device shouldn't be stored in rooms with high humidity.
11. Secure the device during transportation in order to avoid any possible damages. Manufacturer doesn't take responsibility for damages which appeared due to improper preparation of the device during transportation.

CAUTION! This device can be only used inside the buildings.

CAUTION! The device contains small parts which children may swallow.

CAUTION! It is forbidden to make any changes concerning device's structure due to the fact that it is dangerous and it results in loosing warranty.

CAUTION! The weight of user should not be bigger than maximal weight described on page 8 where you will find information regarding this issue.

1) AKCES-MED Sp. z. o. o sells products free from manufacturing defects or faults.
2) Manufacturer gives the purchaser 24-month guarantee from the date of purchase. All defects revealed during warranty period will be repaired free of charge.
3) All defects which appear after warranty period can be repaired only when the user will pay for it. This rule doesn't apply to refunded products - user can ask National Health Refund for refund.
4) Manufacturer claims that the product can be used for 36 months. User can use this product after this period only when he/she will send the device to manufacturer so as to service it. Next, manufacturer determines again how long the product can be used and, moreover, the date of the next service will be determined.
5) If product is damaged, please contact our dealer or AKCES-MED customer service (ph. 17/864 04 70)

10 MAINTENANCE AND CLEANING

CAT II INVENTO™ should be kept clean and used in compliance with the manufacturer's recommendations. The device should be kept in clean, dry and ventilated room. Maintenance as well as cleaning have to be performed at least once a month. Regular cleaning and maintenance of device are indispensable to maintain its correct functionality as well as safety.

It is highly advisable to remember about proper maintenance in order to extend product's aesthetics. So as to do that, it is essential to comply with these guidelines:

1. It is recommended to clean upholstery with the aid of cleaning product, soft sponge and warm water. If you use sponge which is too wet, stain may get bigger, upholstery may be destroyed. It is necessary to remember that the excess of dampness should be removed from fabric before next cleaning. Please rinse upholstery with warm water and clean white cloth once stain is removed.
2. It is forbidden to soak upholstery!
3. It is forbidden to clean upholstery with the aid of hard brushes.
4. It is forbidden to clean upholstery with strong chemical agents such as solvent or caustic chemicals.

CAUTION! Akces-MED. Sp z o. o takes no responsibility for damages caused by use of wrong clearing agent.

5. It is forbidden to soak upholstery during cleaning. Remember that upholstery has to be always dry before using.
6. It is forbidden to clean, make any changes and maintain stroller during using it.
7. All metal as well as plastic elements should be cleaned by hand with the aid of general cleaning products. Remember to familiarize yourself with cleaning product's leaflet.

CAUTION! Remember that upholstery has to be always dry before using!

Before using it is necessary to:

- clean wheels;
- check if base as well as wheels are correctly mounted; check if brake stops turning wheel;
- make sure that all wooden parts e.g. tray don't have splinters;
- check if stroller construction is free of breaks or any kinds of deformities;
- check if all movable parts are working and all screws, nuts, knobs etc. are correctly tightened;
- check if belts, vests, trunk belts, feet stabilizing belts etc are not frayed; check if buckles and clamps work correctly.

CAUTION! Manufacturer takes responsibility only for hidden faults or damages which appeared despite the fact that user complied with the guidelines.

CAUTION! In case of any damages, it is essential to contact the person who sold you the product.

ORTHOPAEDIC DEVICES MANUFACTURER

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Authorised Dealer

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Our passion – your independence!